Protocol for Onboard Screening and Dockside Testing for PSP
Toxins in Molluscan Shellfish in Federally Closed Waters
November 2007

When the harvest of molluscan shellfish is prohibited due to Paralytic Shellfish Poison (PSP), exceptions to the prohibitions may be authorized provided that such harvests are subject to onboard screening and dockside lot testing for paralytic shellfish toxins in accordance with the following *Onboard Screening and Dockside Testing Protocol for PSP*, hereafter referred to as the Protocol.

I. PERMIT REQUIREMENTS:

Only vessels in possession of an appropriate Exempted Fishing Permit (EFP) issued by the National Marine Fisheries Service (NMFS) may harvest molluscan shellfish from Federal waters closed because of PSP. Vessels granted an EFP must participate in the NMFS Vessel Monitoring System (VMS). All requests for permission to harvest in closed Federal waters must include a statement identifying the shipboard person(s) who has been trained by a National Shellfish Sanitation Program (NSSP) Laboratory Evaluation Officer (LEO) or a US Food and Drug Administration (FDA) marine biotoxin expert to conduct onboard PSP screening using a NSSP recognized method(s). Requests for permission to harvest shall also include a signed statement from the intended receiving processor affirming that he/she understands that each lot of shellfish from a Federally closed harvest area must be kept separate, not sold, and not processed until so authorized by the State Shellfish Control Authority (SSCA). Concurrence from the SSCA in the state of landing shall be obtained by NMFS prior to the issuance of an EFP. Under an EFP, the harvester shall be responsible for notifying the SSCA in the state of landing and in a manner approved by the SSCA that molluscan shellfish is being harvested for delivery to the intended receiving processor.

Failure to comply with the provisions of this Protocol will result in the suspension or revocation of the vessel's EFP.

Costs associated with meeting the requirements of this Protocol, including sample collection, screening, transportation, analysis, etc., shall be borne by the industry user.

II. HARVEST LOT:

A harvest lot is defined as all molluscan shellfish harvested during a single period of uninterrupted harvest activity within a geographic area not to exceed three (3) square miles. Once harvesting has ceased and the harvest vessel moves to another location, regardless of the distance, a new harvest lot will be established. Any harvest vessel containing more than one lot shall clearly mark and segregate each lot while at sea, during off loading, and during transportation to a processing facility. Prior to harvesting in Federal waters, each harvest vessel shall submit to the NMFS a written

onboard lot segregation plan. The SSCA in the intended state of landing and the FDA Regional Shellfish Specialist must approve the proposed lot segregation plan.

III. ONBOARD PSP SCREENING PRIOR TO COMMERCIAL HARVESTING

Prior to commercial harvesting of molluscan shellfish, a minimum of five (5) screening samples shall be collected within each area of intended harvest (lot area) and tested for PSP toxins in accordance with a NSSP recognized screening method. Each screening sample shall be collected during a separate and distinct gear tow. Screening sample tows shall be conducted in a manner that evenly distributes the five (5) samples throughout the intended harvest area (lot area). Only shipboard officials trained in the use of the designated NSSP screening method may conduct these tests. Each of the five (5) samples must test negative for PSP toxins. A positive result from any one (1) sample shall render the "lot area" unacceptable for harvest. The harvest vessel captain shall immediately report all positive screening test results, by telephone, to the SSCA within the intended state of landing and the NMFS. The Captain should also notify other permitted harvest vessels of the positive screening test and advise them to avoid the questionable area. For each screening test, positive and negative, the remaining sample material (homogenate) shall be maintained under refrigeration. Test kits, positive and negative, shall accompany the remaining sample homogenates to the certified laboratory. Confirmatory testing shall be performed on homogenate from each positive screening test using a NSSP recognized test method. Upon request by the SSCA in the state of landing, confirmatory testing of homogenate from negative screening tests shall be conducted using a NSSP recognized test method.

Each screening sample shall be comprised of at least twelve (12) whole animals with the exception of mussels and "whole" or "roe-on" scallops. For mussels each sample shall be comprised of thirty (30) animals. For "whole" scallops each sample shall be comprised of twenty (20) scallop viscera and gonads. For "roe-on" scallops each sample shall be comprised of twenty (20) scallop gonads.

All screening results shall be recorded on the "Declaration of Harvest Record" as stipulated in Section V of this Protocol. Test kits used to screen each lot shall accompany the "Declaration of Harvest Record". Upon landing of the harvest vessel, the "Declaration of Harvest Record" and accompanying test kits shall be provided to the individual (state shellfish official, FDA official, NMFS official) authorized to sample the harvested shellfish as described in Section V of this Protocol.

IV. APPROVED LABORATORIES:

Confirmatory PSP analyses shall be according to NSSP recognized methods and shall be conducted by laboratories certified in accordance with NSSP guidelines. Private laboratories may be used if certified by a Federal or state shellfish Laboratory Evaluation Officer (LEO) in accordance with NSSP guidelines.

V. DECLARATION OF HARVEST RECORD:

For each harvesting trip the Captain or Mate shall record the following information on a "Declaration of Harvest Record." Electronic logging of this information may be permitted provided it is made available to the authorized individual at dockside.

- Vessel name and Federal Fishing Permit number
- Name and telephone number of the vessel Captain and vessel owner
- Date(s) of harvest
- Number of lots and volume of catch per lot or number of containers per lot
- Location(s) of harvest (GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds)
- Identification of each harvest lot, including cage tag numbers for surfclams and ocean quahogs, and container numbers or identification codes for other shellfish species.
- Location (GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds) of each PSP screening sample
- Results of each PSP screening test. Screening test kits for each sample shall be submitted to the authorized authority along with the "Declaration of Harvest Record" as stated in Section III
- Destination(s) and purchaser(s) of each lot and amount of each lot to each destination

The Captain or Mate shall sign the "Declaration of Harvest Record." The "Declaration of Harvest Record" shall be checked by the individual authorized to sample the harvested shellfish. Failure to provide complete and accurate information will result in revocation or suspension of the NMFS EFP and rejection of the entire lot(s) of harvested shellfish. Four (4) copies of the "Declaration of Harvest Record" shall be prepared. One (1) copy shall remain with the vessel, one (1) copy shall be provided to the SSCA in the state of landing, one (1) copy shall accompany the catch to the processing firm(s), and one (1) copy shall be retained by the laboratory authorized to conduct lot sample analyses.

VI. CONTAINER LABELING:

Each container of shellfish shall be clearly labeled with the following NSSP required information at the time of harvest:

a) For surfclams and ocean quahogs existing NMFS tagging requirements

b) For all other molluscan shellfish (including Stimpson clams also known as Arctic surfclams) using Tyvek tags:

- Vessel name
- Type and quantity of shellfish

- Date of harvest
- Harvest lot area defined by GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds

VII. NOTIFICATION PRIOR TO UNLOADING:

Each vessel shall give at least twelve (12) hours notice to the individual authorized to sample prior to unloading shellfish. Notice of less than twelve (12) hours may be approved by the authorized individual at his/her discretion. SSCAs may approve industry sampling and sample transport to the NSSP certified testing laboratory in accordance with the practices and procedures used by the SSCA under the NSSP. Such procedures may be approved by the SSCA only when sample collection and sample transport training is provided by the SSCA.

VIII. UNLOADING SCHEDULE:

Unloading shall take place between 7:00 A.M. and 5:00 P.M. Monday through Friday, unless otherwise mutually agreed upon by the individual authorized to sample, the processing plant manager, the harvest vessel captain, and the SSCA in the state of landing, sample testing, and processing.

IX. ACCESS FOR DOCKSIDE SAMPLING:

Individuals authorized to sample shall be provided access to the catch of shellfish.

X. DOCKSIDE SAMPLING, TESTING, AND PRODUCT DISPOSITION:

After dockside samples are collected, molluscan shellfish may be processed while awaiting PSP analytical results. Each lot must be identified and segregated during storage while awaiting dockside sample test results. Under no circumstances will product be released from the processor prior to receiving satisfactory paralytic shellfish toxin test results.

The dockside sampling protocol for molluscan shellfish shall be as follows:

1. For each lot of molluscan shellfish, seven (7) composite samples, each comprised of at least twelve (12) whole animals, shall be taken at random by the individual authorized to sample, with the following exceptions:

    a. For each lot of mussels, seven (7) composite samples, each comprised of at least thirty (30) whole animals, shall be taken at random by the individual authorized to sample.

    b. For each lot of “whole” scallops, seven (7) composite samples, each comprised of twenty (20) scallop viscera and gonads, shall be taken at random by the individual authorized to sample.

c. For each lot of “roe-on” scallops, seven (7) composite samples, each comprised of twenty (20) scallop gonads, shall be taken at random by the individual authorized to sample.

2. Shellfish samples collected in accordance with X.1 shall be tested for the presence of paralytic shellfish toxins using NSSP recognized methods.

3. If test results of any one (1) of the seven (7) samples collected in accordance with X.1 equal or exceed 80ug of paralytic shellfish toxins/100g of shellfish tissue (n=7, c=0), the entire lot must be discarded or destroyed at the cost of the harvester under the supervision of the SSCA in accordance with state laws and regulations except when:

   A lot of “whole” or “roe-on” scallops equals or exceeds 80ug paralytic shellfish toxins/100g of tissue, the adductor muscle may be shucked from the viscera and/or gonad and marketed. The remaining materials (viscera and/or gonad) must be discarded or destroyed under supervision of the SSCA in accordance with state laws and regulations.

4. Laboratory test results for each lot of shellfish shall be forwarded to the SSCA in the state in which the shellfish is being held prior to the product being released for processing by the SSCA.

XI. RECORD KEEPING:

Record keeping requirements shall be as follows:

a) The vessel shall maintain the “Declaration of Harvest Record” for at least one year.

~~b)~~ The processor(s) shall maintain the “Declaration of Harvest Record” for at least one year or two years if the product is frozen.

c) The SSCA in the state of landing shall retain the “Declaration of Harvest Record” for at least two years.

d) FDA shall maintain records of all onboard screening tests and laboratory tests. These data shall be transmitted to the FDA in accordance with Section XII.

XII. EARLY WARNING/ALERT SYSTEM:

PSP sample data acquired as a result of onboard screening and dockside testing shall be transmitted to a central data register to be maintained by the FDA. These data, both screening and confirmatory, shall be transmitted to the FDA by the NSSP

certified laboratory conducting PSP analyses of the sampled lot(s) within one week of the completion of the PSP analyses. The data provided shall include the following:

a) shellfish species
b) harvest location name and coordinates (GPS or latitude/longitude)
c) harvest date
d) onboard screening test method, date, and results
e) laboratory test date and test results

Results of all samples having acceptable levels of paralytic shellfish toxins (<80ug/100g) shall immediately be reported to the SSCA in the state of landing. If the results of any one (1) sample equal or exceed 80ug/100g the testing laboratory shall immediately notify the FDA Regional Shellfish Specialist, the SSCA, and the processor by telephone. The FDA shall notify the NMFS. The NMFS shall notify permitted harvesters to advise them to cease fishing in the affected area(s).

XIII. FEDERAL WATERS UNDER THE JURISDICTION OF THE STATE OF MAINE

The NMFS will not issue an EFP to fish Federal waters of the Maine Mahogany Quahog Zone unless the state of Maine concurs with the issuance of such a permit.

XIV. PROTOCOL EVALUATION:

The protocol and the data it generates will be evaluated annually. The evaluation will be conducted by a work group comprised of state and Federal agencies and the shellfish industry. The evaluation will assess the Protocol's effectiveness in providing public health protection and the need for possible modifications. The evaluation will also allow the possible incorporation of new technology and innovation.